No. 15-1549

United States Court of Appeals for the Federal Circuit

LIFENET HEALTH,
Plaintiff-Appellee,

v.

LIFECELL CORPORATION,
Defendant-Appellant.

Appeal from the United States District Court for the Eastern District of Virginia, Case No. 2:13-CV-486, Judge Henry Coke Morgan, Jr.

BRIEF OF PLAINTIFF-APPELLEE LIFENET HEALTH

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CERTIFICATE OF INTEREST

Counsel for Plaintiff-Appellee certifies the following:

1. The full name of every party represented by me is:

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2. The name of the real party in interest represented by me is:

LifeNet Health

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners or associates who appeared for LifeNet Health in proceedings before the United States District Court for the Eastern District of Virginia, or are expected to appear in this Court, are:

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STATEMENT OF RELATED CASES

No other appeal has been taken in this case. Counsel for LifeNet Health are not aware of any cases in this or any other court that will directly affect or be directly affected by this Court's decision in this appeal.

It should be noted, however, that on September 8, 2015, defendant-appellant LifeCell Corporation filed a complaint for a declaratory judgment against LifeNet Health in the United States District Court for the District of New Jersey with respect to U.S. Patent No. 9,125,971 (the '971 patent), which is part of the same patent family as U.S. Patent No. 6,569,200, the patent at issue in this appeal. *LifeCell Corp. v. LifeNet Health*, No. 3:15-cv-06701 (D.N.J.). Also on September 8, 2015, LifeCell filed a petition with the U.S. Patent and Trademark Office for *inter partes* review of the '971 patent, IPR2015-01888.

INTRODUCTION

This case arrives here after a two-week jury trial during which LifeCell repeatedly told the judge and jury that the outcome would turn on the conflicting testimony of the parties' experts. LifeCell promised that its expert, Dr. Stephen Badylak, would "provide a lot of illumination" on critical questions related to infringement and validity. (A8715; A8709; A9530-31.) And LifeCell appreciated that those critical issues would "unquestionably be for the jury" to resolve after hearing from the experts. (A8700-01; A8279.) But when all was said and done, the district court did "not find Dr. Badylak a persuasive witness" (A9), and, as the verdict makes plain, neither did the jury. The jury found, and the court confirmed in its detailed opinion rejecting LifeCell's post-trial motions, that LifeCell was liable for infringement, had failed to prove invalidity, and owed damages of nearly $35 million.

On appeal, LifeCell's tune has changed dramatically. No longer front-and-center, Dr. Badylak has been relegated to a single mention by name on page 58 of LifeCell's brief. And his disappearance reflects a deeper problem: in an apparent effort to secure a more favorable standard of review, most of LifeCell's brief tries to recast factual issues as legal issues and to turn this case into something it is not. LifeCell's attempted diversions are wrong and misleading.

At its core, this appeal is a sufficiency-of-the-evidence challenge masquerading as a claim construction argument. The central dispute all along has been whether LifeCell makes and sells soft tissue grafts that include an "internal matrix" impregnated with so-called plasticizers (compounds that preserve the tissue while maintaining its internal structure) which "are not removed *from [the] internal matrix* of [the] graft prior to transplantation," as required by the claims of LifeNet's U.S. Patent No. 6,569,200 ('200 patent). (*E.g.*, A93(24:14-16).) There is no dispute related to the construction of that limitation. In the district court and on appeal, LifeCell has been happy to accept the plain meaning of that limitation, and LifeCell *agreed* with LifeNet on the meaning of "internal matrix." This structural limitation requiring that plasticizers remain in the graft's internal matrix simply recognizes that in the grafts claimed in the '200 patent, the plasticizers bound in the internal matrix of the graft are essential to preserving the tissue and protecting the scaffold structure of the internal matrix and thus remain in the internal matrix. That requirement is perfectly consistent with the '200 patent's specification and prosecution history; as a result, the claims are infringed when a graft is made and sold, regardless of what a surgeon may or may not later do to alter the product.

With no true claim construction argument, LifeCell tries to bury the real issue. Its appeal hinges on the contention that its entire soft tissue graft is actually

the same thing as what the '200 patent, and the agreed claim construction, call the internal matrix *of* the soft tissue graft. LifeCell's theory of the case was that its products could not infringe if any plasticizer was removed from anywhere in its grafts before transplantation, because the graft and internal matrix are one and the same.

But, beyond being inconsistent with the claim language and agreed construction, LifeCell's graft-equals-matrix assertion rested—and still rests—on a factual dispute. LifeNet's expert, Dr. David Kaplan, testified that the internal matrix is only a part of the graft and that any plasticizer that might come out of LifeCell's *grafts* before transplantation was not removed from the *internal matrix* of those grafts. On the other side, Dr. Badylak belittled Dr. Kaplan's testimony concerning the internal matrix and touted LifeCell's contrary position "with 100 percent confidence." (A8820.) Evidently sharing that confidence, LifeCell acknowledged multiple times that this was a dispute for the jury to decide (*e.g.*, A8699-701; A9536-40), and the jury's decision was unequivocal: LifeCell infringes. Although LifeCell routinely glides over a distinction that the claims make precise—indiscriminately alternating between referring to removal of plasticizer "from the graft" and removal "from the internal matrix" of the graft—it cannot hide the fact that this issue was hotly contested at trial. The jury and the court rejected LifeCell's view, and no amount of repackaging can change that.

The remainder of LifeCell's arguments are no better, and LifeCell is right to treat them as afterthoughts. As for infringement, LifeCell complains that it does not make and sell a "plasticized soft tissue graft" because the court's claim construction should have required the grafts to be "dehydrated," by which LifeCell apparently means "desiccated." But the claims do not include a separate "dehydrated" limitation or require a particular moisture content, and the specification uses the word "dehydrated" to refer to, among other things, liquid substitution, and does not require grafts to be desiccated. The court's construction thus correctly reflects the patent's text. Meanwhile, LifeCell's own evidence showed that its infringing grafts contained substantially less water than the tissue from which they were made, establishing that liquid substitution of plasticizer for water had occurred. As for invalidity, there is no indefiniteness problem with a limitation that describes a structural property of an infringing graft, and ample evidence supported the jury's decision to credit Dr. Kaplan over Dr. Badylak and to conclude that LifeCell failed to provide clear and convincing evidence that the '200 patent is anticipated or obvious. The Court should affirm.

STATEMENT OF ISSUES

1. Whether substantial evidence supports the jury's verdict of infringement when

a. LifeNet's expert was more persuasive and credible than LifeCell's expert on the factual question of whether LifeCell infringes under claim constructions that LifeCell supported and to which it agreed; and

b. LifeCell does not contest that it makes and sells a "plasticized soft tissue graft" as that term was properly construed, but instead proposes an erroneous construction that reads an unsupported "dehydration" requirement into the claims.

2. Whether the district court correctly rejected LifeCell's defense that the product claims of the '200 patent are invalid as indefinite, where LifeCell's defense rested on the erroneous assertion that a claim limitation that describes the physical structure of the claimed grafts actually defines a method step to be performed by third parties.

3. a. Whether substantial evidence supports the jury's determination that LifeCell failed to prove by clear and convincing evidence that the asserted claims of LifeNet's '200 patent are invalid as anticipated by U.S. Patent No. 4,357,274 (Werner); and

b. Whether the jury and district court properly concluded that LifeCell had failed to prove by clear and convincing evidence that the asserted claims of LifeNet's '200 patent would have been obvious in light of Werner and the knowledge of a person of ordinary skill.

STATEMENT OF THE CASE

I. The Proceedings Below

On September 6, 2013, LifeNet filed this action, alleging that LifeCell, by making and selling various plasticized soft tissue products, infringed claims 1-4, 7, 8, and 10 of LifeNet's '200 patent. (A337-46.) The parties briefed claim construction during the summer of 2014, and the district court issued its *Markman* ruling on July 16, 2014. (A56-69.) The court thereafter denied motions for summary judgment by both parties.

LifeNet's infringement claims and LifeCell's invalidity defenses were tried to a jury between November 3 and 18, 2014. The jury found that LifeCell infringed the asserted claims and that those claims were not invalid, and awarded LifeNet damages of $34,741,971. (A70-77.) LifeCell moved for judgment as a matter of law and a new trial. After briefing and oral argument, the district court denied LifeCell's motions on March 18, 2015. (A1-55.) LifeCell appealed.

II. Statement of Facts

A. The Parties

LifeNet is a nonprofit corporation with its headquarters in Virginia Beach, Virginia. (A337.) Pursuant to its "Saving Lives, Restoring Health" mission statement, LifeNet facilitates the transplantation of more than 400 organs and distributes more than 400,000 biological implants each year. (A337-38.) LifeNet develops and promotes pioneering technologies related to all aspects of the

biological implant production process, including disinfection, decellularization, preservation, and sterilization. (*Id.*)

LifeCell is a Delaware corporation with its principal place of business in New Jersey. (A386.) LifeCell is in the business of making and selling various medical products, including soft tissue graft products. (A339; A386.) Several of those products are at issue here: Strattice Reconstructive Tissue Matrix, Conexa Reconstructive Tissue Matrix, AlloDerm RTM Ready to Use, and GraftJacket Reconstructive Tissue Matrix Ready to Use. (A9471.) Strattice and Conexa are made from porcine skin; AlloDerm RTU and GraftJacket RTU are made from donated human skin. (A8203; A8232-33; A8235-37; A8251-52.) These LifeCell products have been extremely successful, generating revenues for LifeCell of more than $1 billion between 2008 and 2013. (A8404.) As the jury found, each of these products utilizes the LifeNet technology claimed in the ’200 patent.

B. LifeNet’s Technology and the ’200 Patent

1. Soft Tissue Grafts

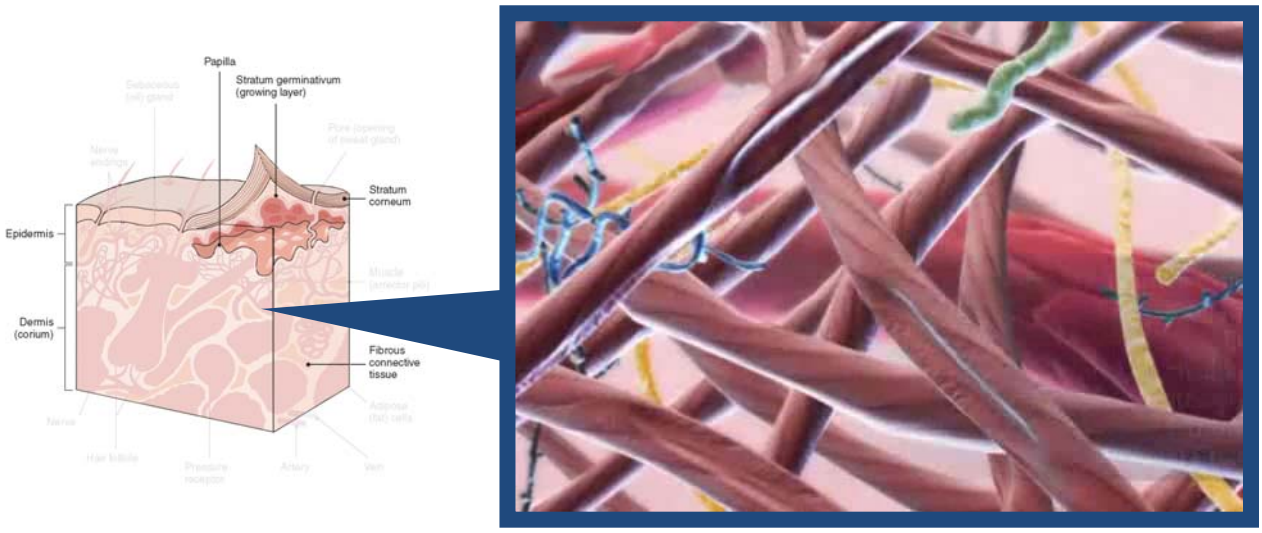
The technology at issue involves soft tissue grafts for use in treating human patients. Soft tissue grafts can be made from donated human tissue or from animal—most commonly, porcine—tissue. (A64; *see also, e.g.*, A386; A764.) “Soft tissue” is a general term that refers to a variety of non-bone tissue structures. (A85(7:12-16, 8:3-8).) These structures can be load-bearing or non-load-bearing.

(A83(3:28-31).) An example of the latter is skin or dermis. (A85(8:3-8).) Examples of the former include pericardium (tissue covering the heart), fascia lata (the sheath covering muscle), dura mater (tissue covering the brain), and various tendons and ligaments. (*Id.*) Soft tissue grafts are used in a variety of applications, including for treatment of burn victims, reconstructive surgery for cancer patients, and repair of torn and damaged ligaments in athletes. (A83(3:26-28).)

Whether the source material is human or animal tissue, the preparation of a soft tissue graft involves a cleaning process that removes cellular material and small molecular weight solutes from the tissue. (A8187, A8189.) Removing these substances is important because, if they are not removed and are included in a graft transplanted into a human patient, they can transmit disease and also lead to rejection of the graft when the patient's immune system detects foreign DNA. (A4; A9260-61.)

What remains after cleaning is critical to the '200 patent's invention. After removing cellular material, the tissue structure includes gaps or voids, where cellular material previously resided, and the underlying "internal matrix" of the tissue, which is essentially a scaffold or framework of components like collagens, elastins, fibronectins, and polysaccharides. (A8188; A8191.) In LifeNet's invention, after cleaning, that internal matrix is intact and structurally sound, and each of the fibers and components that makes up the internal matrix is maintained

in the same orientation and relative organization as it had prior to cleaning. (A8191-92.) This is important because it maintains the material properties of the soft tissue, including the tissue's strength and flexibility. (A8191.) The illustration below depicts the internal matrix of a soft tissue graft after cellular material has been removed (*see* A8190-92):



The gaps or voids in the tissue graft leave room for the diffusion of water. (A8191-92.) Water exists within the soft tissue in three different forms. (A8192.) "Bulk" or "free" water flows outside the tissue and freely moves in and out of the voids in the tissue by simple diffusion. (A8192-93.) It does not, however, interact with the internal matrix scaffold. (A8193, A8194-95.) "Loosely bound" water molecules, on the other hand, interact with the internal matrix scaffold by binding together with other "loosely bound" water molecules to create a shell around hydrophobic portions of the internal matrix scaffold. (A8193.) This interaction is very stable. (*Id.*) "Tightly bound" water also interacts with the internal matrix,

binding tightly to components of the internal matrix by sharing a hydrogen bond with certain portions of those components. (A8194.)

Because soft tissue grafts are originally derived from a human or animal donor, a soft tissue graft must be preserved and stored in order to be useful as a medical product. Prior to the invention in LifeNet's '200 patent, soft tissue products were preserved by freezing or, more typically, freeze-drying. These preservation methods came with a variety of disadvantages. Frozen tissue had to be shipped on ice, stored in a freezer, and carefully thawed prior to use. (A82(1:8-13).) Freeze-dried tissue did not require refrigeration, but the prior-art process of freeze-drying altered the material properties of a soft tissue graft, leaving it with the pliability and flexibility of a piece of cardboard. (A9670; A83(3:44-55).) This meant, among other things, that freeze-dried soft tissue grafts had to be rehydrated before they could be transplanted, a process that could consume an hour of valuable operating-room time. (A83(3:55-58); A9603-04; A9670.) Beyond the cost and delay resulting from the need to rehydrate the graft, these prior art soft tissue products also presented an increased risk of disease transmission and increased immunogenicity, and could yield toxic degradation products. (A83(4:60-65).)

2. The Invention of the ’200 Patent

All of this changed with the invention disclosed and claimed in LifeNet’s ’200 patent. LifeNet developed a new way to process soft tissue grafts so that they no longer had to be refrigerated, frozen, or freeze-dried prior to use. The resulting soft tissue products had physical, chemical, and biological properties comparable to native tissue, but could be stored for extended periods without freezing and could be used without the need to waste time in the operating room on thawing or rehydration.

LifeNet’s solution to the problems presented by prior art grafts involved replacing what are called the “waters of hydration”—*i.e.*, water molecules—in a cleaned soft tissue graft with one or more plasticizers. (A85(8:14-17).) As inventor Dr. Lloyd Wolfinbarger explained, the water in a soft tissue graft played an important role in maintaining the structure of the tissue after cellular material was removed. (A9633.) Water, however, can also lead to tissue degradation and bacterial growth, which is why prior art preservation techniques focused on removing water, despite the adverse effects on tissue structure and physical properties. (*Id.*) The insight reflected in the ’200 patent was that a cleaned soft tissue graft could be impregnated with a plasticizer, such as glycerol, to replace the waters of hydration. The plasticizer would then perform the same stabilizing function of the water without allowing the degradation and bacterial growth that

water would produce. (A9632-33.) Although glycerol and similar compounds had been used in certain freezing procedures in the past, the novelty of the '200 patent's invention was the recognition that the "plasticizers" would maintain the internal structure of the tissue through the interactions with the internal matrix, allowing it to be as flexible and pliable as native tissue and preserving the framework or scaffold within which the graft recipient's cells could grow. (A9632.) And, importantly, all of this would be possible with a soft tissue graft product that could be stored at room temperature for as long as four years, would have the same properties as native tissue, and would be ready to use in the operating room without further preparation. (A8009-10.)

This process of replacing waters of hydration with glycerol or other compounds that displace or replace water at the molecular level is called "plasticization" in the '200 patent. As with the water in a soft tissue graft, plasticizer exists in a soft tissue graft in several forms. Plasticizer will interact with the bulk water and move freely in and out of the tissue by simple diffusion. (A8195.) This plasticizer can easily be removed from the tissue because it is outside the tissue or in the voids in the tissue and does not interact with the components of the internal matrix. (A8196; A8246-47.) Some of the plasticizer, however, interacts with the loosely bound water and replaces some of it by interacting with hydrophobic regions of the components of the internal matrix in

place of the water. (A7947; A8195; A9617.) And some plasticizer will displace some of the tightly bound water and bind with the internal matrix components in place of the water. (A8195-96.) The plasticizer that replaces the tightly and loosely bound water is very difficult to remove from the internal matrix. (A8196.) This tightly and loosely bound plasticizer keeps water from changing—and preserves—the properties of the internal matrix. (A8212-13; A8247.)

LifeNet filed the original application seeking patent protection for its plasticized soft tissue graft invention in 1998. That original application covered both bone and soft tissue graft products and methods for making both. Pursuant to a restriction requirement, LifeNet separated its bone and soft tissue claims into separate applications. Claim 16 of the soft tissue divisional application is generally representative of the original form of the soft tissue claims:

> 16. A plasticized soft tissue graft suitable for transplantation into a human, comprising:
> a cleaned soft tissue graft having an internal matrix; and
> one or more plasticizers contained in said internal matrix.

(A169-77.) The claims captured the inventors' critical advance of producing a cleaned soft tissue graft with an internal matrix that contained a plasticizer. The Examiner, however, rejected the original claims as anticipated by U.S. Patent No. 5,718,012 (Cavallaro). (A183-85.)

Cavallaro involved a very different invention—specifically, a process for strengthening individual collagen fibers, not for preserving a plasticized soft tissue

graft having an internal matrix as a whole, without changing its material properties. As the Examiner saw it, "Cavallaro forms collagen threads" and, "[t]o improve tensile strength, a collagen thread or bundle comprising collagen threads is plasticized." (A184.) But as Cavallaro itself explained, to be effective, its strengthening process required that the plasticizer be removed from the collagen fibers before use: "Plasticizing agents such as glycerol or other hygroscopic agents known in the art may possibly be used, but in order for strength to be preserved after conditioning treatment, the plasticizer must also be removed." (A547(7:40-43).) LifeNet responded by noting that plasticizer was *not* removed in its invention, a structural feature for which there was support "throughout the specification." (A192-93.) LifeNet amended its claims to make this inherent structural feature express, adding the phrase "said one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human" to each pending claim. (A192-96.) The claims were allowed and the '200 patent issued shortly thereafter with no further action. (A81; A197.)

The patent includes product claims directed to plasticized soft tissue grafts and method claims directed to methods for producing such grafts. Claim 1 is representative of the product claims:

> 1. A plasticized soft tissue graft suitable for transplantation into a human, comprising:

> a cleaned soft tissue graft having an internal matrix; and
> one or more plasticizers contained in said internal matrix; said one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

(A93(24:10-16).) Claim 7 is representative of the method claims:

> 7. A method for producing a plasticized soft tissue graft suitable for transplantation into a human, comprising:
> impregnating a cleaned, soft tissue graft with one or more plasticizers to produce a plasticized soft tissue graft, and said one or more plasticizers are not removed from an internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

(A93(24:39-45).)

C. This Litigation

LifeNet filed this action in 2013, alleging that LifeCell infringes both product and method claims of the ’200 patent by making and selling plasticized soft tissue products. The litigation was, from the outset, hotly contested. LifeCell raised a host of defenses, including not only noninfringement and invalidity, but also laches, patent exhaustion and implied license, and failure to mark, most of which have been abandoned.

Claim construction, in particular, was vigorously contested, and the limitation that plasticizer is “not removed from [an/said] internal matrix of said plasticized soft tissue graft prior to transplantation” was a focus. This dispute centered on whether the limitation required that no plasticizer be removed (LifeCell’s position) or allowed for some, but not all, to be removed (LifeNet’s

position). The district court agreed with LifeCell that the claim language was clear—"not removed" meant no removal (A1609)—and that the term therefore required no construction. (A1613.) Interestingly, there was no dispute at the claim construction stage as to the site from which the plasticizer was not to be removed—the constructions proposed by both parties specified, as did the claims themselves, that the plasticizer was not to be removed from the internal matrix of the soft tissue graft. (A1522.) And the parties agreed that the "internal matrix" is "the intercellular substance of such soft tissue including for example ligaments and tendons, including collagen and elastin fibers and base matrix substances." (A1521; A1622-23.)

The district court issued its claim construction order on July 16, 2014, construing eight terms disputed by the parties, and adopting their agreed constructions for three terms, including "internal matrix." (A56-69.) One of the disputed terms was "plasticized soft tissue graft." The court construed that term based on the specification's express definitions of "plasticizer" and "soft tissue graft" to mean:

> a load-bearing and/or non-load-bearing soft tissue product, including skin, pericardium, dura mater, fascia lata, and a variety of ligaments and tendons composed of an internal matrix where free and loosely bound waters of hydration in the tissue have been replaced with one or more plasticizers without altering the orientation of the collagen fibers, such that the mechanical properties, including the material, physical and use properties, of the tissue product are similar to those of normal hydrated tissue.

(A62-63.) Although there had been some discussion in the claim construction arguments about including a separate "dehydrated" requirement, the parties ultimately agreed that "dehydrated" would have been redundant, because the construction's reference to replacing "waters of hydration" with plasticizer incorporated the specification's description of "dehydrated." (A1581-82.)

The case went to trial based on these claim construction rulings. At trial, LifeCell focused on the requirement that plasticizer not be removed from the internal matrix of the claimed soft tissue grafts, and emphasized that it instructed users of its grafts to soak or rinse them in saline for two minutes before transplanting them into a patient.[1] This saline rinse, LifeCell argued, would remove plasticizer from its *grafts*, as both parties agreed. But LifeCell went on to argue, based on testimony from its expert Dr. Badylak, and notwithstanding the agreed construction of "internal matrix," that its grafts and the internal matrix of its grafts were one and the same. Therefore, according to LifeCell, any plasticizer removed from a graft was necessarily removed from the internal matrix, so the soft tissue graft product was outside the scope of the asserted claims.

For its part, LifeNet explained, via its expert Dr. Kaplan, that a soft tissue graft and the internal matrix of a soft tissue graft are not the same thing. Dr.

[1] It was undisputed, however, that LifeCell grafts can safely be used without the saline rinse. (A12; A8832-35.)

Kaplan explained that a cleaned soft tissue graft consists of an internal matrix structure, as well as gaps and voids, the result of cleaning the cellular elements away, into which water and plasticizer can flow. Dr. Kaplan described, as explained above, the different ways in which water and plasticizer react with and bind to the components of a soft tissue graft. His testimony and other evidence demonstrated that LifeCell's products use glycerol as a plasticizer. (A4; A8215.) Because of the chemical structure and properties of glycerol, that glycerol replaces the loosely and tightly bound water in the internal matrix of LifeCell's tissue grafts, and binds very strongly to and forms very stable interactions with the components of the internal matrix (A8195; A8314), so much so that this plasticizer is "in the molecular structure" of the internal matrix (A82(1:13-23)).

In fact, the evidence showed that the only way to remove this glycerol from the internal matrix of the LifeCell grafts would be to disrupt the structure of the internal matrix itself. (A8196, A8198.) Doing that, in turn, would alter the material properties of the graft which then would no longer match those of native tissue in structure and function. (A8198, A8200.) This would make the soft tissue graft undesirable for use in clinical implantation because it would no longer mimic the properties of native tissue. (*See* A8217.) As described by Dr. Kaplan:

> [S]o as long as [the internal matrix] bundles stay intact and in their same orientation with respect to each other, that means you preserve the native structure of the tissue, and in turn the native function of the tissue. If you've disrupted those bundles, you're going to destroy that

> internal matrix, you're changing the orientation and structure, and then you change the function; the tissue doesn't have the same mechanical properties after you do that.

(A8200; A8234-35.) LifeCell acknowledges that its two-minute rinse did not remove all plasticizer from its grafts. Br. 17-18. And, based on LifeCell's own tests confirming that the native structure of the tissue is maintained even after the rinse, Dr. Kaplan determined that the plasticizers in LifeCell's products are not removed from the internal matrix prior to transplantation. (A8198; A8247-48; A8318.)

After a two-week trial, the jury found that LifeCell's accused soft tissue products infringed the '200 patent. It also found that LifeCell had failed to establish any of its invalidity defenses, which included enablement and anticipation and obviousness based on a variety of references beyond the Werner reference on which it relies on appeal. (A70-76.) The jury awarded LifeNet $34,741,971 in damages. (A77.) LifeCell filed post-trial motions under Rules 50 and 59. After extensive briefing and oral argument, the district court denied LifeCell's motions in a detailed, 55-page opinion. (A1-55.)

SUMMARY OF ARGUMENT

I. The jury properly concluded that LifeCell infringes the '200 patent because, among other things, it makes and sells "plasticized soft tissue graft[s]" in

which the "plasticizers are not removed from [the] internal matrix of [the] plasticized soft tissue graft prior to transplantation into a human." (A93.)

LifeCell's appeal focuses on the limitation requiring that plasticizer remain in the internal matrix of a plasticized graft, but its many attempts to convert the factual dispute presented by that limitation into legal questions all fail. The dispute at trial was between the parties' experts and concerned whether or not LifeCell makes and sells a graft that meets this limitation. LifeNet's expert testified that it did and explained why, providing, as the district court noted, "a detailed description" of the underlying science. (A8-9.) LifeCell's expert said LifeCell did not infringe because, in his view, the internal matrix of LifeCell's grafts is simply another term for the entire graft itself, and because some plasticizer can be removed from the graft as a whole if the graft is rinsed, it must be removed from the internal matrix. The jury quite sensibly agreed with LifeNet, and the district court observed that LifeCell's expert had been thoroughly discredited (A9; A54). There is no reason to upset those determinations here.

Nor is there any problem with the claim constructions that *LifeCell* supported and to which it agreed below. The relevant limitation reflects the fact that in the grafts claimed in the '200 patent, plasticizers are introduced into the internal matrix to preserve the tissue, without the need for freeze-drying or freezing, and to maintain the tissue's internal scaffold structure, and thus are not

removed and remain in the internal matrix. And, properly viewed as a limitation that describes a structural characteristic of the internal matrix of the graft—and does so in precise terms—LifeCell's arguments about that limitation all fall apart. There was no "Dr. Kaplan claim construction" (he testified about infringement, using the district court's claim construction), no *O2 Micro* issue (LifeCell agreed with the court's claim construction, and there was no unresolved dispute), no prosecution disclaimer (the limitation was added to clarify the inherent structural properties of the claimed grafts), and no divided infringement (by describing a structural property, the limitation does not require transplantation or any other action by a third party). LifeNet proved, and the jury properly held, that LifeCell makes and sells grafts in which "plasticizers are not removed from [the] internal matrix of [the] plasticized soft tissue graft prior to transplantation into a human."

LifeCell also makes and sells "plasticized soft tissue grafts," as that term was correctly construed. LifeCell's contention that the claim should have been read to include a "low residual moisture" or "dehydration" requirement cannot be squared with the claims or specification. The claims do not use the term "dehydration" or include any particular moisture requirement. "Dehydration," as used in the specification, describes liquid substitution, and does not require the total or near desiccation that LifeCell urges now. The district court's construction

correctly accounts for the teachings of the specification, and LifeCell infringes under that construction.

II. LifeCell's invalidity arguments suffer from the same fundamental deficiencies as its noninfringement arguments. Its indefiniteness argument is simply a repackaged version of its misreading of the limitation requiring that plasticizer is not removed from the internal matrix of the graft prior to transplantation. That limitation defines the structure and properties of the claimed product—it does not direct or require a surgeon or anyone else to do anything to complete the claimed invention, unlike the cases on which LifeCell relies. And whether the '200 patent was anticipated by or obvious in light of the Werner patent was a pure battle of the experts. LifeNet's Dr. Kaplan explained why Werner did not disclose a "cleaned" or "plasticized soft tissue graft" required by the claims of the '200 patent; LifeCell's Dr. Badylak disagreed; and the jury (and district court) credited Dr. Kaplan. Those determinations should be affirmed.

STANDARD OF REVIEW

The trial court's decision on a motion for judgment as a matter of law is reviewed *de novo*, "draw[ing] all reasonable inferences in [LifeNet's] favor without weighing the evidence or assessing the witnesses' credibility." *Johnson v. MBNA Am. Bank, NA*, 357 F.3d 426, 431 (4th Cir. 2004); *see also SSL Servs. LLC v. Citrix Sys., Inc.*, 769 F.3d 1073, 1082 (Fed. Cir. 2014) (this Court applies

regional circuit law). "The question is whether a jury, viewing the evidence in the light most favorable to [LifeNet], could have properly reached the conclusion reached by this jury. [The Court] must reverse if a reasonable jury could only rule in favor of [LifeCell]; if reasonable minds could differ, [the court] must affirm." *Johnson*, 357 F.3d at 431 (citation omitted).

As for infringement, the jury's determination that LifeCell infringes the '200 patent "is a question of fact that is reviewed for substantial evidence." *SSL Servs.*, 769 F.3d at 1082. The district court's "ultimate construction of the claim[s]" is a "legal conclusion" reviewed *de novo*, with the court's resolution of any "underlying factual dispute" reviewed for clear error. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

LifeCell presented several invalidity defenses for which it has the burden of proof by clear and convincing evidence. *E.g.*, *SSL Servs.*, 769 F.3d at 1089. Indefiniteness is a legal conclusion reviewed *de novo*, although "[a]ny fact critical to a holding on indefiniteness must be proven by … clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1365, 1366 (Fed. Cir. 2003). Anticipation is a question of fact, reviewed for substantial evidence. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002). "Obviousness is a question of law based on specific factual findings," and the

jury's underlying findings of fact, presumed from the verdict, are reviewed for substantial evidence. *SSL Servs.*, 769 F.3d at 1082, 1089.

ARGUMENT

I. THE JURY CORRECTLY FOUND THAT LIFECELL INFRINGED THE '200 PATENT.

The jury found that LifeCell's soft tissue products infringe product claims 1-4 and that its process for making those products infringes method claims 7, 8, and 10 of LifeNet's '200 patent. Each of those claims calls for a "plasticized soft tissue graft" in which "plasticizers are not removed from [the] internal matrix of [the] plasticized soft tissue graft prior to transplantation into a human." (A93.) Dr. Kaplan testified that, under the district court's claim construction, LifeCell makes and sells products that meet those limitations and, as a result, it infringes the asserted claims. The jury and the judge believed Dr. Kaplan. There is no basis to disturb that well-supported conclusion.

A. LifeCell Makes and Sells Products in Which Plasticizers Are Not Removed from the Internal Matrix of the Graft Prior to Transplantation.

Most of LifeCell's brief, like the trial, focuses on the requirement in the asserted claims that "plasticizers are not removed from [the] internal matrix of [the] plasticized soft tissue graft prior to transplantation into a human." (A93.) Unlike the trial, however, most of LifeCell's brief mischaracterizes as a legal issue what everyone had agreed was a factual dispute: whether LifeCell's products met

this limitation under claim constructions LifeCell had endorsed. That incongruity should doom LifeCell's appeal.

1. The Patent Requires That Plasticizers Are Not Removed from the Internal Matrix of the Graft.

The '200 patent covers plasticized soft tissue grafts. (A81.) As explained above, the invention works by removing cellular matter from the native tissue, leaving behind a scaffolding structure that the patent refers to as the "internal matrix," as well as the voids left by the cellular matter, which are filled with a preservative known as a plasticizer. (A4.) The plasticizer serves several functions—among other things, it allows the tissue to remain ready to use and be stored for extended periods at room temperature and also helps maintain the original structure of the internal matrix, which is critical to the tissue's utility. (*Supra* § I.A.2.) But not all plasticizer molecules interact with the tissue and its internal matrix in the same way—some plasticizer molecules bind to the tissue's internal matrix components or create a protective shell around them, while most interact with the "free" or "bulk" water in the tissue and move freely in and out of the gaps in the tissue where cellular matter used to be. (A4.) Recognizing this characteristic of the invention, each of the asserted claims expressly provides that the "one or more plasticizers are not removed from [the] internal matrix of [the] plasticized soft tissue graft prior to transplantation into a human." (A93.)

The district court construed this term to, in LifeCell's words, "mean what it says," Br. 37: plasticizers are not removed *from the internal matrix of the graft*. (A3.) That plain-meaning construction recognizes that the internal matrix is part of, but not the same thing as, the graft. That conclusion is compelled by the claim language, which refers to a soft tissue graft "having an internal matrix" and to plasticizer not being removed "from said internal matrix of said plasticized soft tissue graft" (A93), as well as the agreed construction of "internal matrix" as "the intercellular substance *of* such soft tissue…" (A62 (emphasis added)). The claims, and claim construction, set out precisely *from where* in the graft plasticizers are "not removed." They are not removed from and remain in the internal matrix of the tissue graft; the claims are not directed to whether plasticizers are or are not removed from the graft as a whole. (A93.)

In line with the claim language, the specification clearly differentiates between plasticizer bound in the internal matrix and plasticizer that may be associated with the graft more broadly. The specification, for example, explains that the "invention replaces water *in the molecular structure* of the bone or soft tissue *matrix* with one or more plasticizers." (A82(1:14-15) (emphases added).) The specification notes that a brief wash might "remove any remaining traces of plasticizer associated with the immediate surfaces of the grafts" (*i.e.*, some bulk or free plasticizer) and that a longer wash could "remove as much plasticizer as

possible" (*i.e.*, more bulk or free plasticizer, but not *all* plasticizer). (A87(12:8-16).) The specification also describes how, even when using a centrifuge to remove "excess" plasticizer, "[t]he plasticizer tightly associated with the molecular and chemical structure of the tissue"—*i.e.*, the plasticizer bound to the internal matrix—"will not exit the graft and the tissue will remain plasticized without retaining physically discernible quantities of plasticizer." (A87(11:65-12:2).)

The distinctions reflected in the claim language and specification reflect structural characteristics that are essential to the invention. In particular, the limitation describes a property of the patented soft tissue graft—*i.e.*, the graft has an internal matrix, or scaffold, whose structure is preserved through plasticization, making the graft particularly well suited for transplantation. The "Summary of the Invention," for example, states that "[t]he present invention solves prior art problems of grafts *having insufficient materials properties*, graft brittleness, and the necessity for rehydration prior to clinical implantation, by providing a plasticized dehydrated bone and/or soft tissue *product that exhibits materials properties that approximate those properties present in normal hydrated tissue*, is not brittle and does not necessitate rehydration prior to implantation." (A84(5:33-40) (emphases added).) As the district court explained, "it is clear that the binding of the preservative/plasticizer to the internal matrix is crucial to the ability of the

soft tissue graft to retain its similarity to a normal hydrated tissue" and offer better transplantation results. (A54.)

The court's understanding that this limitation describes a structural property of the claimed tissue graft is also fully consistent with the '200 patent's file history. As LifeCell is eager to point out, the language was added to the original claims in response to a rejection based on Cavallaro. (A184; A192-93.) Cavallaro did not, as LifeCell asserts, "disclose[] cleaned, plasticized soft tissue grafts," Br. 15, but rather involved a method for increasing the tensile strength of *individual* collagen threads by exposing them to a plasticizer, which is then removed after conditioning to complete the process. (A1500(Abstract); A1504(7:42-43) ("[I]n order for strength to be preserved after conditioning treatment, the plasticizer must also be removed.").) In other words, the Cavallaro invention will not work unless the plasticizing agent is removed. In the '200 patent, in contrast, the plasticizing agent is used to preserve the tissue and maintain the structure of the internal matrix of the tissue graft, and must remain in the internal matrix to do so. In Cavallaro, the plasticizer is not used, as it is in the '200 patent, to *preserve* the native orientation and structure of the matrix; it is used to increase the strength of collagen threads by *altering* them—*i.e.*, plasticizing the collagen, elongating it, and then removing

plasticizer. (A1504(7:34-53).)[2] LifeNet's amendment, which in effect said "this invention is not what Cavallaro's is," simply clarified that the '200 patent claims an invention nothing like Cavallaro's. (A192-93.)

2. There Was Sufficient Evidence for a Reasonable Jury to Conclude That LifeCell's Products Meet This Limitation.

The question whether LifeCell infringes under the district court's plain-meaning construction pitted Dr. Kaplan against Dr. Badylak. As the court explained, the "major dispute … centered on whether plasticizers were removed from the internal matrix of [LifeCell's] products by soaking the grafts in a saline solution for two minutes, as stated in [LifeCell's] Instructions for Use." (A8.) The parties presented diametrically conflicting views.

Despite having previously agreed on the construction of "internal matrix," LifeCell's theory was that the entire tissue graft was the internal matrix and that, because a two-minute soak removed some plasticizer from its grafts, it necessarily removed plasticizer from the internal matrix. That was LifeCell's argument at summary judgment. (*See* A1653-54.) And it was Dr. Badylak's testimony at trial. (*See, e.g.*, A8752 ("to me, Strattice and products like Strattice are internal matrix");

[2] Cavallaro also teaches that the strengthening method can be applied to "bundles" of collagen threads. (A1505.) But there is no original scaffolding of these bundles, which are not naturally occurring but instead are constructed by processes like "knitting and weaving." (A1503(5:51-53).) As with the individual threads, these bundles are plasticized, elongated, and stripped of plasticizer to increase tensile strength, not to preserve any original structure. (A1504(7:27-56).)

A8839 ("In my opinion, the entire thing is the extracellular matrix or internal matrix"); A8865; A9537 ("Dr. Badylak held it up and said the whole tissue is the internal matrix.").) In short, because there were tests showing that some plasticizer came out of *the graft* if a two-minute rinse was performed (*e.g.*, A8849-65), LifeCell argued that plasticizer necessarily came out of the internal matrix; therefore, it did not make and sell products in which "one or more plasticizers are not removed from [the] internal matrix of [the] plasticized soft tissue graft prior to transplantation" (A93).

LifeNet's evidence proved otherwise: any plasticizer escaping from LifeCell's grafts during any two-minute rinse did not, in fact, come from the internal matrix. Dr. Kaplan testified that plasticizer chemically bound to the components of the internal matrix of the LifeCell grafts—essential to maintaining the matrix's structure—is not removed prior to transplantation, even if a rinse is performed. (*See, e.g.*, A8198-200.) Any plasticizer recovered from *the graft* during a rinse was the free or bulk plasticizer that was not bound in the internal matrix and thus was not removed from the internal matrix. (*See, e.g.*, A8230; A8246; *see also* A8191-200 (explaining technology).) LifeCell repeatedly tried to get Dr. Kaplan to agree that LifeCell's grafts are themselves internal matrices, but he refused to adopt that factually erroneous position. (*See, e.g.*, A8274-75; A8314; A1920 ("LifeNet does not agree with Dr. Badylak's statement that the 'internal

matrix' represents the entirety of the tissue graft.").) Indeed, after LifeCell's counsel continued to ask Dr. Kaplan whether plasticizer was removed "from the graft," and Dr. Kaplan continued to articulate the difference between removal from the graft and from the internal matrix, the court recognized that the questions were "a little bit misleading" and permitted Dr. Kaplan to reiterate that "the solution being removed [in a rinse] … is from the free water solution containing the plasticizer but not from the internal matrix." (A8309-10.)

LifeCell's liability for infringement thus turned on a factual question, and everyone knew it. LifeCell told the court that "[w]here the [two sides] part company is, according to [Dr.] Kaplan, [plasticizer coming out during a soak is] not coming out of the internal matrix," while Dr. Badylak would contend that "it indeed comes out of the internal matrix." (A8699-700.) And LifeCell left no doubt that the "question will unquestionably be for the jury" and that the experts' credibility on this score would "be an issue for the jury." (A8700-01; *see also* A9536-40 (closing argument).) In the end, "the Court, and apparently the jury, found Dr. Kaplan's testimony more persuasive than that of Dr. Badylak." (A54; *see also* A9.) Because "[t]he district court credited [LifeNet's] expert and found [LifeCell's] expert unreliable," and because LifeCell "makes no effort to dislodge the court's credibility findings" and cannot show any error in those findings, the

Court should affirm the judgment of infringement. *MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.*, 731 F.3d 1258, 1269 (Fed. Cir. 2013).

3. LifeCell's Efforts to Reframe the Dispute on Appeal Are Meritless.

Faced with a well-supported jury verdict upheld in a careful and detailed post-trial opinion, LifeCell desperately tries to change the subject. LifeCell's repeated efforts to muddy up this factual issue were squarely rejected in the district court and should be again here.

a. LifeCell Repeatedly Mischaracterizes the Record.

First of all, there is the matter of terminology. Throughout its brief, LifeCell casually switches back and forth between referring to what LifeCell apparently wishes the claims said (no removal from the graft) and something closer to what the claims actually say (no removal from the internal matrix). *Compare, e.g.*, Br. 5 (claiming the patent requires "that plasticizer not be removed *from the graft*") (emphasis altered) *and id.* at 38 ("LifeCell's construction [is that] plasticizer is either removed or not removed from the graft prior to transplantation") *with id.* at 37 ("from the internal matrix"). Not once, however, does LifeCell use the actual terminology of the claims, which say that plasticizer is not removed from the internal matrix *of the graft* (A93), choosing instead to adopt the shorthand "Not Removed Limitation" and thus conveniently avoid the actual claim language, Br. vii.

LifeCell did the same thing below, but neither the court nor the jury bought the false equivalence. When, for example, LifeCell moved for summary judgment based on the argument that the '200 patent "forbids removal of any 'plasticizer' *from a soft tissue graft* prior to its transplantation into a patient" (A1640 (emphasis added)), the district court's order denying the motion recognized that "[i]f the plasticizer does not come from the internal matrix, but rather comes from the exterior of the graft, then there would be no removal from the internal matrix." (A7429.) And at trial, moreover, the court found "very frustrating" LifeCell's "repeatedly" "say[ing] 'removed from the internal matrix' and then the next time … say[ing] 'removed' without saying 'from the internal matrix.'" (A8702.) The limitation is about removal from the internal matrix of the graft, not the graft as a whole.

At its most extreme, LifeCell goes so far as to try to affiliate LifeNet with its mistaken view, declaring that "the uniform trial testimony … was that the internal matrix *is the graft.*" Br. 35. That is simply false. Not only is it contrary to the claim language and the agreed construction of "internal matrix" (*infra* note 4), but Dr. Kaplan testified repeatedly that the graft contains the internal matrix *plus* gaps and voids in which bulk water or plasticizer sits. (*See, e.g.*, A8188; A8275.) And LifeCell understood perfectly well that Dr. Kaplan's testimony did not equate the graft and the graft's internal matrix when, for example, it told the district court that

"Dr. Kaplan is arguing that there are, what he calls voids in the tissue. This will be a factual dispute between experts … he says that those voids are not considered to be part of the tissue matrix. That is relevant to the issue of not removed and where the plasticizer comes from." (A8279.) As LifeCell promised, its expert, Dr. Badylak, testified that there were no voids in the tissue. But LifeNet demonstrated that his testimony was contradicted by LifeCell's own scientists (*e.g.*, A9046, A9048, A9052, A9055),[3] and the jury evidently rejected it. On this record, there is no basis for pretending the parties agreed that, contrary to the claim language (A93), the internal matrix "is the graft," Br. 35 (emphasis omitted). (*See also* A8197 (LifeCell acknowledges LifeNet's contrary position).)[4]

But LifeCell's word-choice tactics are indicative of a more fundamental misconception because much of its brief is premised on a fiction: there is no such

[3] His contention that there is no such thing as free or bulk water (*e.g.*, A9071), was likewise directly contradicted by LifeCell's own documents (*e.g.*, A9074-76), and was contrary to the unchallenged construction that "plasticized soft tissue graft" is a product in which "free and loosely bound waters of hydration" have been replaced with plasticizer (A1521).

[4] The fact that the specification refers to a graft "'composed of an internal matrix,'" Br. 35, does not help LifeCell. The claim language controls, and it refers to a soft tissue graft "having an internal matrix" and uses the term "from said internal matrix of said plasticized soft tissue graft," plainly indicating that the internal matrix is a part of the graft but not coextensive with it. (A93.) LifeCell recognized this when it agreed to the construction of "internal matrix." (A1521 ("the intercellular substance *of* such soft tissue.") (emphasis added); *see also* A84(6:63) ("internal matrix" defined as "the intercellular substance *of* such soft tissue.") (emphasis added).)

thing as "Dr. Kaplan's claim construction." Br. 25-40. Dr. Kaplan merely testified, as most experts do, about the technology at issue and why LifeCell's products infringe under the district court's claim construction. The parties agreed on the construction of "internal matrix" (A62), and the claims are clear that they are directed to whether or not plasticizer is removed from the internal matrix (A93). Dr. Kaplan testified about the plasticizer in the internal matrix of the accused products, which is bound to the structural components and thus "not removed" from the internal matrix (*e.g.*, A8191-200; A8230-31), in contrast to the plasticizer that flows in and out of the gaps or voids in the tissue and replaces the tissue's free or bulk water. Determining whether plasticizer is removed from the internal matrix of the accused products, of course, requires knowing what plasticizer is in the internal matrix in the first place. Contrary to LifeCell's suggestion on appeal, Br. 26, neither side suggested below that whether plasticizer was "contained in" or "removed from" the internal matrix was a matter for claim construction. Rather, everyone agreed that this was a factual question to be resolved based on the evidence, including expert testimony. (*E.g.*, A8514 (district court: whether plasticizer is removed from the internal matrix is "the key to the infringement"); A8700 (LifeCell counsel: whether plasticizer comes out of the internal matrix "will unquestionably be for the jury").) Dr. Kaplan and Dr.

Badylak gave conflicting testimony on that factual question, and the jury (and the court) believed Dr. Kaplan. (A54-55.)[5]

LifeCell notes that it unsuccessfully tried to make a claim construction issue out of a factual question in the district court, Br. 26-27, but that is exactly the point: the court understood that Dr. Kaplan was *not* construing the claims, but was applying the court's construction to the accused products. LifeCell, for example, filed a motion *in limine* arguing, among other things, that the court should "clarify that plasticizers cannot be 'deliberately remov[ed]' *from the grafts* at any point prior to transplantation." (A6086 (emphasis added).) The court instead held that LifeNet "may offer testimony that the plasticizers removed do not come from the internal matrix." (A7609.) When LifeCell tried to turn this ruling into something more, maintaining that "Dr. Kaplan's opinion regarding the removal of 'nonbound' plasticizers contradicted the Court's claim construction [and] violated the Court's *in limine* order" (A7672), the district court twice told LifeCell it was misconstruing the decision (A8495; A8686; *see also* A8196-98; A8227-29). Dr. Kaplan's

[5] In a similar vein, LifeCell mischaracterizes Dr. Kaplan's testimony about what removing the plasticizer from the internal matrix of the accused products would do. Br. 30-31, 36. He said removal would change the structure of the LifeCell products in a way that would adversely affect their mechanical properties, not that it would literally destroy the grafts. (A8198.) And he did not testify that plasticizer could never be removed from the internal matrix of any graft, because he was talking specifically about LifeCell's products—and the particular plasticizers used in making those products. (A8198; A8203-31 (Strattice); A8234-35 (Conexa); A8240 (Alloderm); A8253, A8257-58 (GraftJacket).)

testimony that plasticizer would remain in the internal matrix because it was bound to the structural components of the internal matrix of the accused products was "consistent with the claim construction because the focus [wa]s still on removal from the internal matrix." (A23.)

Finally, LifeCell points to the *Markman* hearing to argue that Dr. Kaplan's trial testimony conflicted with LifeNet's position there. Br. 35-37. Wrong again. The issue at the *Markman* hearing concerning this limitation was not about what it means for plasticizer to be "removed from" the internal matrix,[6] or whether the internal matrix is the same thing as the graft. And in all events, what mattered at trial was not LifeNet's *Markman* arguments but that the district court adopted a plain-meaning construction of the term, which LifeCell gladly accepted. (*See, e.g.*, A1609.)[7] That is what Dr. Kaplan was required to and did apply in his trial testimony.

[6] The argument was about *how much* plasticizer was removed, rather than *how* or *from where*, and, as LifeCell requested, the court construed the term to require that no plasticizer be removed from the internal matrix. (A1557-58; A1605-13.)

[7] To be clear, LifeCell distorts the record here, too. Among other things, Dr. Kaplan's declaration did not say that "'rehydration' or 'washing' would 'remove plasticizer(s) from the internal matrix'" of the graft. Br. 36. Rather, it said that, under the '200 patent and unlike prior technology, plasticizer need not be removed from the internal matrix of a plasticized graft prior to transplantation—the graft thus "does not require rehydration, or even washing." (A1220 (citing A84(5:22-28)).)

b. LifeCell's Attempts to Bootstrap Its Mischaracterizations into Legal Errors All Fail.

Correcting LifeCell's mischaracterizations reveals that the "claim construction" issues LifeCell presents are nonexistent. First, LifeCell invokes *O2 Micro Int'l Ltd. v. Beyond Innovation Tech.Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008), to argue there was a fundamental dispute over the meaning of the claims that the court failed to resolve. Br. 25-27. There was not. The fundamental dispute at trial was over *where* the plasticizer that LifeCell said was removed from its grafts was removed from. The claims focus on removal from the internal matrix of the graft, and LifeCell's discredited expert focused on the graft as a whole and attempted to equate the two. (*Supra* § I.A.2.) The fact that Dr. Badylak fumbled over the meaning of "internal matrix"—a term whose construction the parties agreed on (A62)—provides no basis for suggesting the district court failed to construe a different term or somehow delegated a claim construction dispute to the jury. *See, e.g.*, *Function Media, L.L.C. v. Google, Inc.*, 708 F.3d 1310, 1324-27 (Fed. Cir. 2013) (declining to extend *O2 Micro*); *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1334-35 (Fed. Cir. 2010) (same); *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1207 (Fed. Cir. 2010) (same).

More fundamentally, even putting this misconception to one side, there still was no open claim construction issue to be resolved. The district court construed the limitation requiring that plasticizer not be removed from the internal matrix of

the graft to mean that no plasticizer is removed, just as LifeCell requested. (A1609.) Because that was exactly what the claim language said—not removed means not removed—the court properly held that no further construction was required. (A1613.) In the court below, and on appeal, LifeCell does not argue that the court erred in this regard or offer a different construction, but asserts only that the court was required to "clarify" what LifeCell had agreed was the plain meaning of the claim language.[8] LifeCell offers no support for the proposition that a district court commits reversible error by declining to restate plain claim language that required no special construction to begin with. Moreover, the supposed clarification that LifeCell proposed—"no plasticizers are removed from the internal matrix prior to transplantation," Br. 37—does nothing more than restate the claim language, and is precisely the construction Dr. Kaplan applied in his testimony.

Next, LifeCell confuses the prosecution history and Dr. Kaplan's infringement testimony to make a convoluted argument about surplusage. Br. 27-32. LifeCell's contention seems to be that (1) Dr. Kaplan's testimony that plasticizer could not be removed from the internal matrix of the accused LifeCell products without significantly altering their material properties meant that, as a

[8] As LifeCell told the district court, it did not ask the court to change its construction, only "to elaborate and explain it to the jury" (A10072) by telling the jury that "the words 'not removed' mean no removal" (A10073).

matter of claim construction, no plasticizer can ever be removed from any graft's internal matrix, (2) this would render the claim term "meaningless" surplusage, but (3) that would be impermissible because the limitation was added as a narrowing amendment during prosecution. *Id.* None of LifeCell's reasoning is correct.

To begin with, and as explained above, Dr. Kaplan's testimony concerned removing plasticizer from the internal matrix of the *LifeCell* products, not whether plasticizer can or cannot be removed from the internal matrix of every conceivable potentially infringing product. Testimony about LifeCell's products says nothing about whether another product might have a different structure, different plasticizers and other components, and different properties. Whether a hypothetical product in which plasticizers are or can be removed from the graft's internal matrix without rendering it unsuitable for transplantation would infringe the '200 patent is not the issue presented here or the issue addressed by Dr. Kaplan.[9]

[9] For similar reasons, the verdict is not inconsistent with the district court's comments that transplantation is relevant to the infringement analysis. *E.g.*, Br. 37, 47. Most of the claims, after all, concern a product that is "suitable for transplantation into a human," making the purpose for which the grafts are designed and made (transplantation) directly relevant. (*See, e.g.*, A14.) As the district court explained, "the claim is infringed if the graft was suitable for transplantation, as [LifeCell]'s own expert testified." (A14; *see also, e.g.*, A10061.) The evidence showed that LifeCell's products infringe when made and sold because they are plasticized soft tissue grafts suitable for transplantation, and plasticizer is not removed from their internal matrices before transplantation. "Thus, whereas infringement was not complete in *Aristocrat* and *Muniauction* until

Nor is LifeCell correct to characterize the amendment adding this limitation as one that necessarily narrowed the claim scope. Claim amendments are not automatically narrowing, even when they add language in response to a rejection. *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111 (Fed. Cir. 2001), is instructive. There, the patentee added a limitation in response to a rejection in a new claim while canceling the rejected claim, expressly stating what had not been explicit in the canceled claim. *Id.* at 1125. But because the original claim already contemplated what was clarified by the amendment, this Court recognized that the amendment "only redefined the … limitation without narrowing the claim." *Id.* at 1126; *see also, e.g.*, *Intelligent Computer Solutions, Inc. v. Voom Techs., Inc.*, 509 F. Supp. 2d 847, 860-61 (C.D. Cal. 2006) (finding that addition of term after prior art rejection did not narrow patent's claims but distinguished it from prior art); *cf. VDP Patent, LLC v. Welch Allyn Holdings, Inc.*, 623 F. Supp. 2d 364, 377-78 (S.D.N.Y. 2007) (recognizing that "an amendment to clarify a claim description may give rise to estoppel, [but] it will do so only where the amendment is also deemed to have narrowed the proposed claim").

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the users interacted with the systems, here the surgeons were provided a graft that actually infringed and whose method of production infringed." (A14.) If another product made in a different way, with different components and properties, were at issue, the infringement analysis might lead to a different conclusion.

This is what happened here—the amendment merely made express a structural characteristic already inherent in the invention as originally claimed. Before amendment, the pending claims recited a "plasticized soft tissue graft" and, in most instances, one "suitable for transplantation." (A93.) But if plasticizer were removed from the internal matrix, the graft would no longer be a "plasticized" soft tissue graft suitable for transplantation. (*See, e.g.*, A9741 (inventor testifying that "[i]f you remove the plasticizer you … don't have a plasticized tissue"); A412 (LifeCell acknowledging that a "plasticized soft tissue graft" must contain plasticizer); A1099 (same).) More than that, the patent explains that the plasticizer is essential to maintaining the structure of the tissue's internal matrix, and the limitation thus recognizes that plasticizer must remain in the internal matrix to serve that purpose. By adding language to make clear that the plasticizers in the '200 patent play a very different role from the plasticizers in Cavallaro (*supra* § I.A.1), LifeNet merely clarified the parameters of its invention.[10]

[10] LifeCell is also wrong to contend that LifeNet's amendment meant that the claims now require direct implantation and cannot be met if a graft is washed. Br. 16, 33-34. LifeNet told the PTO that "[s]upport for th[e] amendment appears throughout the specification," and included one example that allows for direct implantation without preparation. (A192-93.) That citation did not purport to be narrowing; what mattered (before and after amendment) was whether plasticizer is removed from the internal matrix.

Lastly, LifeCell finishes with a flurry of arguments directed to the proposition that the ’200 patent requires transplantation and thus depends on the actions of third-party surgeons. Br. 38, 45-49. It does not. (*See* A10-14.) Functional language in a claim may describe the structure or a capability of a claimed device, *e.g.*, *Microprocessor Enhancement Corp. v. Tex. Instruments Inc.*, 520 F.3d 1367, 1375 (Fed. Cir. 2008), including when expressed in the negative, *e.g.*, *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1329 (Fed. Cir. 2003) (holding “not isolated from human urine” was a requirement concerning the source of the claimed composition); *Synqor, Inc. v. Artesyn Techs., Inc.*, 2010 WL 2991037, at *30-31 (E.D. Tex. July 26, 2010) (“‘is not driven into saturation’ … is used to describe the structure and capabilities of the claimed apparatus.”), *aff’d on other grounds*, 709 F.3d 1365 (Fed. Cir. 2013). And when the actions of a third-party do not change the structure of the device—and thus whether it is infringing when made and sold—they do not affect the direct infringement question. *See, e.g.*, *Fantasy Sports Props., Inc. v. Sportsline.com, Inc.*, 287 F.3d 1108, 1118 (Fed. Cir. 2002) (infringing software must include a means for performing a function “regardless whether that means is activated or utilized in any way” because “the user is only activating means that are *already present in the underlying software*”).

The ’200 patent requires that plasticizers “are not removed from [the] internal matrix of [the] plasticized soft tissue graft prior to transplantation.” (A93.)

As in *Amgen* and *Synqor*, that language describes the structure and properties of the claimed "plasticized soft tissue graft." LifeNet's amendment made that clear, but it did not "limit how the plasticized soft tissue graft is used surgically," Br. 5, or otherwise impose a requirement for use of the graft, for surgery involving the graft, or for preparation of the graft for transplantation, *id.* at 6, 52. The claims did not require transplantation before the amendment and do not do so after.

By the same token, LifeCell is wrong to think it can escape infringement liability because "independent surgeons," rather than LifeCell, are the ones who allegedly practice the invention. Br. 45-49. LifeCell makes and sells products that practice the invention, and LifeCell obtains the patented technology's benefits when it offers products with a long shelf life that can be stored without refrigeration, and used without rehydration. (A10-14.) As the district court appreciated, therefore, this case is not at all like *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (Fed. Cir. 2005), and the others LifeCell cites. Br. 45-49. In those cases, no infringing product or system existed at all unless a third party took an affirmative step to complete or add something to the structure or system as it existed when it left the defendant's hands. Here, by contrast, the final product that leaves LifeCell's hands is complete and, the testimony showed, infringes in that condition without any affirmative action by anyone else. Unlike the alleged infringers in those cases, LifeCell knows its

product infringes without needing to wait to see how anyone else behaves.[11] The fact that a future actor hypothetically might try to alter a LifeCell product by removing plasticizer from its internal matrix—which Dr. Kaplan explained would fundamentally change its properties (*see supra* note 5)—does not change the fact that the product as made and sold was an infringing structure. The jury and district court committed no error in holding LifeCell liable for such infringing conduct.

B. LifeCell Makes and Sells "Plasticized Soft Tissue Grafts," as Properly Construed by the District Court.

Finally getting to a claim construction argument that actually is about claim construction, LifeCell takes issue with the district court's construction of "plasticized soft tissue graft." Br. 40-44. The court construed that term, based on express definitions in the specification, to mean "a load-bearing and/or non-load-bearing soft tissue product, including skin, pericardium, dura mater, fascia lata, and a variety of ligaments and tendons composed of an internal matrix where free and loosely bound waters of hydration in the tissue have been replaced with one or more plasticizers." (A2-3; *see* A85(7:29-35, 8:3-9).) LifeCell thinks the construction should also require that the tissue is desiccated. LifeCell is wrong.

[11] Indeed, in LifeCell's invalidity case, Dr. Badylak confirmed that "not removed from the internal matrix prior to transplantation" is a structural limitation not dependent on third-party actions. He testified that two prior art references, neither of which required a surgeon to do anything, disclose the "not removed from the internal matrix" limitation of the asserted claims. (A8923-24; A9005-06.)

For one thing, LifeCell's primary argument amounts to the proposition that an admittedly redundant word—"dehydrated"—was necessary to the construction. (*See* Br. 41; A1581.) At the *Markman* stage, the court found, and LifeCell agreed, that the definition of dehydrated was already part of the claim construction because the claim construction requires that "free and loosely bound waters of hydration in the tissue have been replaced with one or more plasticizers." (A1581 (calling "correct" the court's statement that "it says in the definition the water has been removed … [and] all that does is define dehydrated"); A402 ("Replacing this free and loosely bound water with plasticizers means the tissue product is dehydrated."); A1093-94 (same).) Indeed, LifeCell also admitted that it proposed including the word "dehydrated" in the construction merely to "clarify to the jury what that means," which the court correctly saw as unnecessary given that the meaning of "dehydrated" was already included in the construction. (A1582 ("If we tell [the jury] that they remove the water, we don't have to do it by using the term 'dehydration.'").) LifeCell's proposed construction would effectively call for a dehydrated tissue which has been dehydrated—a self-evidently *un*necessary addition.

Beyond advocating for redundancy, LifeCell also proposes importing limitations from particular embodiments into the claims—violating another settled rule of claim construction. *See, e.g.*, *Varco, L.P. v. Pason Sys. USA Corp.*, 436

F.3d 1368, 1373 (Fed. Cir. 2006). In truth, the specification makes clear what the district court's construction captures—"dehydrated" does not mean "desiccated." The specification defines "dehydrated" tissue to include tissue preserved by "liquid substitution" (A84(6:35-39)), and the decrease in water caused by liquid substitution establishes that dehydration may occur by replacing some but not all water with plasticizer and keeping the graft bathed in liquid. (*See, e.g.*, A85(7:24-28); A92(22:55-58) (dehydration by liquid substitution that does not involve desiccation).)

LifeCell is thus incorrect to try to import a "low residual moisture" limitation akin to desiccation into the claims. Br. 42-44. The claims do not require a low moisture content, and the fact that transplantation may occur "without rehydration" is entirely consistent with requiring that some water be removed through plasticization. There is no requirement that all or some fixed amount of water be replaced (A1618; *see also* A9635 ('200 patent inventor: "It was never about how much residual moisture is left.")), and it is telling that LifeCell cannot even make up its mind about what the correct "understanding" of a purportedly fixed amount would be, *see, e.g.*, Br. 43 ("less than about 5%"); (A1582 ("no more than 8 to 10%"); A1617-18 ("less than 10%")). Dehydration by liquid substitution as used in the '200 patent simply means that some of the water is replaced with plasticizer. (A1618.)

Under the correct construction and understanding of "plasticized soft tissue graft," the jury found, and the district court agreed, that plasticizer replaces water in the internal matrices of LifeCell's products. In particular, the evidence demonstrated that water levels in LifeCell's plasticized soft tissue products were significantly lower than in the unplasticized, cleaned tissue. (A9059-70.) That was sufficient to show dehydration (*i.e.*, liquid substitution) under the patent, and LifeCell's arguments to the contrary are meritless. LifeCell's products are "plasticized soft tissue graft[s]."

II. THE JURY AND THE DISTRICT COURT CORRECTLY REJECTED LIFECELL'S INVALIDITY CONTENTIONS.

LifeCell concludes its brief with three half-hearted invalidity arguments. The jury and the district court properly rejected them all.

A. The Asserted Claims Are Not Indefinite.

LifeCell contends that a subset of the claims it was found to infringe (product claims 1-4) are invalid for indefiniteness because they "recit[e] both an apparatus and a method of using that apparatus." Br. 50 (quoting *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005)). In particular, LifeCell argues, the requirement that plasticizer is "not removed from [the] internal matrix of [the] graft … prior to transplantation" (A93) recites a method for using the claimed plasticized soft tissue graft. Br. 50-52. But this is just a replay of LifeCell's erroneous contention that the claims require transplantation.

Patents claiming both a product and a method of making the product often repeat terms, but overlapping language does not convert an apparatus limitation into a method step, or *vice versa*. *See, e.g.*, *Microprocessor*, 520 F.3d at 1374-75. And apparatus claims that do not explicitly require affirmative performance of an action by a user do not include method steps or run afoul of 35 U.S.C. § 112, ¶ 2. *See, e.g.*, *HTC Corp. v. IPCom GmbH & Co.*, 667 F.3d 1270, 1277 (Fed. Cir. 2012); *Synqor*, 2010 WL 2991037, at *30-31.

The asserted apparatus claims here do not require any "use" at all, and the Court need look no further than the language of *all* asserted claims to see why. "[C]laim terms are normally used consistently throughout the patent" and thus usually have the same meaning when appearing across claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). That well-settled principle forecloses LifeCell's indefiniteness argument. Each of the asserted method claims, which LifeCell does not contend are indefinite, recites a "method for *producing*"—not transplanting—"a plasticized soft tissue graft *suitable for* transplantation into a human." (A93 (emphases added).) Like the apparatus claims, those method claims require that in grafts produced by the claimed methods, plasticizer is "not removed from [the] internal matrix of [the] graft … prior to transplantation." (*Id.*) But the only way to read the limitation consistently across the claims is to recognize that it recites a structural feature or property of the graft (*supra* § I.A.1),

and not a "specific requirement met only if surgeons prepare and use the graft in a transplantation procedure without removal of plasticizers," Br. 52. The graft must have that property when "produc[ed]" such that it is "suitable for transplantation," as required in the method claims, and the property is likewise a characteristic of a graft so produced, as required in the product claims. (A93.) In neither case does the limitation require transplantation or depend on use by a surgeon.

Indeed, LifeCell gets the point exactly backwards when it declares that the fact "[t]hat this limitation is a method step is reinforced by the fact that it is recited verbatim as a step in method claim 7." Br. 52. The fact that the limitation appears in identical terms in a method claim for *producing*—not transplanting—the grafts demonstrates that the limitation recites a property of those grafts and not a step in a claimed method. The district court thus correctly held that LifeCell failed to establish that claims 1-4 are invalid as indefinite. (A28; A7432-37.)

B. LifeCell Failed to Present Clear and Convincing Evidence That the '200 Patent Is Invalid in Light of Werner.

LifeCell argued at trial that the '200 patent is anticipated and obvious based on four different prior art references and various combinations of them. (A9485-89.) The jury and the court concluded that LifeCell failed to provide clear and convincing evidence of invalidity under any of its theories. (A28-38; A70-77.) On appeal, LifeCell has abandoned three of its four references, but maintains that a 1982 patent to Werner (A17493-96) anticipates the '200 patent and renders it

obvious. Br. 52-59. The jury heard from Dr. Kaplan and Dr. Badylak on the factual question of what Werner discloses and found Dr. Kaplan more persuasive. LifeCell presents no reason to overturn that verdict and to conclude, instead, that a reasonable jury could only find that clear and convincing evidence established the contrary.

1. Werner Does Not Anticipate the '200 Patent.

LifeCell's argument that Werner anticipates the '200 patent focuses on two limitations: (1) the need for a "plasticized soft tissue graft" and (2) the fact that the graft is "cleaned." Br. 54-57. But "[t]he determination of what a prior art reference discloses is a question of fact" and the "jury was entitled to believe [Dr. Kaplan] and find that [Werner] does not disclose" either one. *Yoon Ja Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1326 (Fed. Cir. 2006). LifeCell has not shown clear and convincing evidence the other way, much less that a reasonable jury could only find as much.

For starters, LifeCell's brief proceeds as if it were *LifeNet's* burden to *disprove* anticipation. Other than a single sentence stating that "LifeCell's expert likewise explained how [Werner] removes cells and cellular elements," Br. 54, LifeCell spends its entire argument trying to attack Dr. Kaplan's testimony for LifeNet. Br. 54-57. It was, however, *LifeCell's* burden to prove—by clear and convincing evidence—that the '200 patent was anticipated, *e.g.*, *Teleflex*, 299 F.3d

at 1323, and the absence of affirmative evidence on that score is telling. Indeed, LifeCell would have this Court overturn the jury's finding that LifeCell failed to prove anticipation while pointing to no evidence on which this Court could base such a decision.

In fact, there is no such evidence. As for the "plasticized soft tissue graft" limitation, LifeCell does not cite a single line of testimony purporting to establish that Werner discloses this limitation, let alone testimony establishing that by clear and convincing evidence. Br. 57 (criticizing Dr. Kaplan's testimony). But even setting aside that fatal deficiency, there was ample reason for the jury to reject LifeCell's contention that Werner discloses a "plasticized soft tissue graft." The district court's construction of that term required, among other things, that plasticization occur "without altering the orientation of the collagen fibers, such that the mechanical properties, including the material, physical and use properties, of the tissue product are similar to those of normal hydrated tissue." (A69.) Dr. Kaplan explained that Werner was not concerned with maintaining the "mechanical properties of the native-like tissue" that is so critical to the '200 patent. (A9279.) Rather, Werner makes "very clear [that] the mechanical

properties *are* altered significantly from native tissue" (A9262), which is what Werner intended.[12]

For his part, Dr. Badylak's testimony was either conclusory or actually contrary to LifeCell's position. On direct, when asked "[n]ow, how do you know, sir, that Werner discloses a plasticized soft tissue graft, as the Court has construed that term," Dr. Badylak replied by restating the question: "Well, I believe it's—I'm not sure what you mean by how do I know. It's described—it meets all of the criteria of the Court's definition of a plasticized soft tissue graft." (A8917; *see also* A8916 ("the Werner patent uses … soft tissue … that is treated with glycerin … and this meets the criteria of a plasticized soft tissue graft. You have plasticized soft tissue, and you treat it with glycerin.").) Apparently satisfied with that "explanation," LifeCell's questioning moved on. (A8917.) And when Dr. Badylak was asked on cross-examination whether the increased tensile strength in Werner showed changes in the mechanical properties, Dr. Badylak first "agree[d]" that Werner's mechanical properties "have changed," before testifying that he could not say one way or the other but was "starting to think [the change in strength] is different." (A9098-99.) The jury was well within its province to conclude, after

[12] Dr. Kaplan did not "concede[] on cross-examination that this was incorrect." Br. 56. He explained that whether or not the strength changes were statistically significant, they still represented changes in the mechanical properties and that Werner was directed to increasing strength rather than maintaining the native structure of the internal matrix. (A9285-92.)

weighing the experts' testimony, that LifeCell failed to prove by clear and convincing evidence that Werner discloses a "plasticized soft tissue graft."[13]

So too was there substantial evidence to support the conclusion that Werner does not disclose a "cleaned" soft tissue graft. The district court construed that term to mean "a process during which cellular elements and small molecular weight solutes are removed." (A64.) This limitation is the focus of LifeCell's argument on appeal, and its position reduces to the proposition that, because *some* cellular elements are removed in Werner (namely, lipids or fat), Werner necessarily meets the court's construction of the "cleaned" limitation. Br. 54-56. But LifeCell acknowledged at trial that this was another factual dispute (A9329 ("Q. I know you and Dr. Kaplan have a disagreement about whether Werner discloses cleaning. Do you understand that? A. I do.")), and the jury properly resolved it in LifeNet's favor.

[13] LifeCell's comment that the '200 patent and Werner both happen to discuss a 30% glycerin solution, Br. 52, changes nothing and certainly is not clear and convincing evidence that the tissue in Werner was plasticized as construed by the district court. Dr. Kaplan testified, for example, that the processes were different (A9294 ("You can't assume [Werner's 30 percent glycerol treatment would result in a plasticized soft tissue graft] because the process he used is different than in the '200 patent," introducing "so many other variables here"), and that one could not conclude that the Werner process would result in a "plasticized soft tissue graft" simply by stating that 30% glycerol was used. (A9263-64; *see also* A9304 ("[W]hether or not 30 percent glycerol results in a plasticized soft tissue graft will depend on many things, including how the cleaning is done"; in fact, it depends "on the entire process used prior to that treatment and the component.").)

The problem with LifeCell's position becomes clear when the court's claim construction is read in the context of the '200 patent as a whole. Starting at the *Markman* stage, it was evident that a person of ordinary skill would understand that a plasticized soft tissue graft suitable for transplantation into a human would need to be "cleaned" such that it would not transmit disease or lead to rejection of the tissue. When LifeCell asked for the term to be construed to mean "at least some cellular elements and/or small molecular weight solutes are removed" (*e.g.*, A1522), LifeNet explained that this proposal was flawed because the construction "must account for the need to avoid any undesirable biological impact upon implantation, including inflammatory and immune system reactions in the recipient" (A1148; *see also* A1047; A1233-36). After LifeNet reiterated the purpose of the '200 patent at the *Markman* hearing, the court adopted LifeNet's construction. (A1596-602.) Again at summary judgment, the court confirmed that "[w]hile the Court's claim construction does not require that all of the cellular elements be removed, the fact that the grafts in Werner were capable of passing disease indicates that they were not 'cleaned.'" (A7439.) Whether Werner disclosed a "cleaned" graft under this construction would be for the jury to decide (A7439-40), and the jury ultimately rejected LifeCell's position.

Nothing about the evidence at trial undermines the jury's conclusion. Dr. Kaplan acknowledged that Werner discussed a two-step "degreasing" process, but

explained why that process did not result in a "cleaned" graft as construed: although "the lipids, the grease materials, will be removed in this process, … all of the other cell components, the DNA, the RNA, the many different proteins in there, none of that is extracted." (A9259-62.) That was "very significant, because if you leave this material in there you're going to have a material that's not going to be very compatible in the body." (A9261.)

LifeCell's presentation certainly did not require a finding that Werner taught this limitation. Dr. Badylak was again equivocal at best. He summarily declared that Werner discloses a cleaned graft because Werner's degreasing process will destroy and rinse out lipids or fat (A8919-20), while simultaneously seeming to appreciate that Werner's process could leave a graft capable of transmitting mad cow disease (A9100-01). At another point, Dr. Badylak testified that "what cleaning is all about" was that "one had to, *as the Court defines it*, clean it, rid the tissue of those antigens, those molecules that cause the recipient to reject it" (A9029 (emphasis added))—precisely what Werner's removal of lipids or fats did not do. *See also* Br. 58 ("If the transplant is going to be put into a patient, one needs to avoid transplant rejection by cleaning the tissue."). And, at closing, LifeCell told the jury that the prior art showed "[t]hat cleaning soft tissue to get rid of the cells, the DNA that makes you you and me me and everybody else in this courtroom unique, is taken out" and that the process in Werner "will lyse or break

or clean the tissues, the DNA" (A9544-47), despite the fact that Dr. Kaplan had clearly testified that "all of the other cell components, *the DNA*, the RNA, the many different proteins in there, none of that is extracted" (A9260 (emphasis added)). There was thus substantial evidence on which the jury could conclude that Werner's removal of some fat and lipids does not establish by clear and convincing evidence that Werner meets the '200 patent's "cleaned" limitation, or that Werner anticipates the '200 patent more generally.[14]

2. Werner Does Not Render the '200 Patent Obvious.

LifeCell's obviousness argument is even more feeble. According to LifeCell, "[e]ven if Werner did not anticipate the asserted claims, at most it would lack a sufficient degree of 'cleaning' the tissue, which would have been an obvious modification to a person skilled in the art at the time of the invention." Br. 57.

There are at least two problems with this assertion. To begin with, LifeCell again asks this Court to grant judgment as a matter of law that LifeCell proved, by clear and convincing evidence, that the asserted claims were obvious without

[14] LifeCell's assertion that "the processing disclosed in the '200 Patent's examples of cleaning soft tissues (examples 9-10) does not remove all cellular elements, but removes 'fat'—exactly the cellular component that Dr. Kaplan admitted Werner removes," Br. 55, misrepresents the record. The witness, LifeNet employee Bud Brame, stated that LifeNet's cleaning process as described in the '200 patent included a wash that removed fat; he did not state that the wash, or additional procedures, would not remove other cellular elements as well. (A8146.) In addition, Mr. Brame had not seen the patent in years, and the court acknowledged that LifeCell was posing questions to Mr. Brame that "[LifeCell had] already established that he didn't know." (*Id.*)

pointing to any evidence that Werner discloses a "plasticized soft tissue graft." Br. 57-58. LifeCell took the same approach in post-trial briefing, and the court properly recognized that LifeCell's contention "ignores the failure of Werner … to disclose a 'plasticized soft tissue graft[.]'" (A36.) Dr. Kaplan testified that, even assuming one of ordinary skill would combine a cleaned tissue with the process of Werner, that would not produce a "plasticized soft tissue graft" because "[y]ou still have changed the mechanical properties, the material features," which the '200 patent does not allow. (A9278-79.) Despite its demanding burden of proof, LifeCell offers this Court no evidence to conclude as a matter of law that Dr. Kaplan was wrong or, more to the point, that LifeCell presented such clear and convincing evidence that no reasonable jury could find otherwise.

Nor was the jury required to conclude that the handful of lines LifeCell cites concerning cleaning technology circa 1998 provided clear and convincing evidence to support an obviousness finding. The questions Dr. Kaplan was asked about whether one of ordinary skill would know how to clean soft tissue and would have reason to do so were not directed to the "cleaned" limitation of the '200 patent (A9307), and Dr. Kaplan elsewhere testified that one of ordinary skill would not have reason to apply Werner to "cleaned" tissue and expect to produce a "plasticized soft tissue graft" (A9279). These factual issues underlying the

obviousness determination were disputed, and substantial evidence supported the jury's verdict for LifeNet.

CONCLUSION

For the foregoing reasons, the Court should affirm the judgments of infringement and validity.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of September, 2015, I caused the foregoing Brief For Plaintiff-Appellee to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit through the Court's CM/ECF system.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) and the Rules of this Court, because it contains 13,967 words as determined by the Microsoft 2007 word-processing system used to prepare the brief, excluding the parties of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

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